REMARKS

After entry of this amendment, claims 1-9 and 11-29 are pending. Claim 10 is cancelled; claims 1 and 11 are amended.

35 U.S.C. § 112 Rejections

Reconsideration of the rejection of claims 1-9 and 14-21 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement is respectfully requested. The claims are original claims and are supported by a commensurate, in fact verbatim, description in the specification. The Office indulges a strong presumption that the written description requirement is satisfied with regard to such claims.[1] However, to expedite prosecution, claim 1 is now amended to include a chemical structure, which describes the methionine or methionine-like moiety. It is respectfully submitted that claims 1-9 and 14-21 fully comply with the written description requirement, and that this ground of rejection should be withdrawn.

Further, reconsideration is respectfully requested of the rejection of claims 1-29 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. As explained below, applicant respectfully maintains that the pending claims are fully enabled. In any event, it is believed that the rejection is obviated by the amendments to claims 1 and 22 to include a chemical structure describing the methionine or methionine-like moiety.

The Office states that the "specification does not enable any person skilled in the art to which it pertains, ... to use the invention commensurate in scope with these claims."[2] However, the authorities establish that a specification that contains a teaching of the manner and process of making and using the invention which corresponds in scope to the claims is presumed to be enabled unless there is reason to doubt the objective truth of the statements contained in the specification.[3] Although the prior art

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[1]M.P.E.P. § 2163.

[2]See Office action dated October 1, 2004 on p. 2.

[3]In re Marzocchi, 169 USPQ 367, 370 (CCPA 1971).

affords no basis for predicting whether a specific sulfur-containing protective agent would be effective against CDDP toxicity, applicant has discovered that toxicities due to radiation (or CDDP) can be treated with the limited range of compounds within the structural formula in claim 1. Moreover, with regard to predictability, none of the ineffective sulfur compounds which applicant discusses in the specification on pages 5-9 fall within the structural formula recited in amended claim 1. And while there still is no basis for predicting the efficacy of many or most species within the wide genus of organic sulfur compounds, applicant's amended claims are directed to the use of only a relatively small subset of the possible sulfur-containing protective compounds. Accordingly, since applicant is claiming only protective agents of the structural formula in claim 1, the Office has not provided a reason to doubt the objective truth that these protective agents are enabled for preventing or treating toxicities from exposure to radiation.

Moreover, inasmuch as there has been no enablement rejection of original claim 10, the provisions of which have now been incorporated into claim 1, it is believed and understood that the instant amendment fully meets the ground of the enablement rejection of claim 1 as articulated by the Examiner in the October 4, 2004 Office action. The Office is, therefore, respectfully requested to withdraw the §112, first paragraph rejection of this claim as based on the scope of definition of the sulfur compound.

Because the definition of the protective agent in claim 22 is fully within the scope of the definition of original claim 10, it is further respectfully submitted that the enablement rejection as set forth in the October 4 action does not apply to claim 22. For this reason, and because the claim is independently submitted to be fully enabled under the principles of Marzocchi and similar authorities, it is respectfully submitted that the §112, first paragraph rejection of this claim, as based on the definition of the sulfur compound, should also be withdrawn. Claim 22 is directed to the administration of either L-methionine or D,L-methionine to a patient exposed to radiation. No other protective agents are encompassed by this claim. The Examiner has offered no reason to doubt the objective truth of the teaching that L-methionine and D,L-methionine are effective against toxicities in a patient exposed to radiation.

Reconsideration is respectfully requested of the rejection of claims 1-29 under 35 U.S.C. § 112 for failure to enable "preventing." The Examiner asserts that generally no compounds in medical science can "prevent" any conditions.[4] However, a medical dictionary defines preventive as "to come before, prevent" and lists prophylactic as a synonym.[5] Accordingly, the term "prevent" is construed using the plain meaning of the term to mean that the agent is administered prior to the event, as it comes before or is a prophylactic. Additionally, "prevent" does not have the same meaning as the term "cure," because in the medical context, cure implies that the agent is administered after the patient has been in a diseased state, since it is defined as a "restoration to health."[6] Therefore, prevention is not synonymous with cure and a method for preventing toxicity as construed above means that the anti-toxic agent is administered prior to the event and it does not require a method for treatment with absolute success.

The claims at issue recite methods of "preventing or treating ototoxicity, neurotoxicity, alopecia, gastrointestinal disorder, or reduced survival in a patient exposed to radiation." The definition of "treat" is to care for a patient medically or surgically.[7] When read in the context of the claims and specification as a whole, the meaning of preventing or treating toxicity is to administer the protective agent of the invention to a subject in need thereof; this administration could be prior to, simultaneous with or subsequent to the onset of toxicity.

Moreover, treating toxicity includes preventing toxicity. To treat (care for a patient medically) toxicity, the care can be prophylactic. In addition, the treatment or care can be simultaneous with or after the onset of the toxicity. Thus, to treat toxicity, the agents are administered prior to, simultaneous with or after the onset of the toxicity; whereas, as detailed above, to prevent toxicity, the compositions are administered prior to the onset of the toxicity. Neither term requires a "cure."

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[4]Page 3 of the Office action dated October 1, 2004.

[5]Stedman's Medical Dictionary, 26th Edition, 1995.

[6]See id.

[7]Stedman's Medical Dictionary, 26th Ed., 1995.

The Claimed Compounds are Not *prima facie* Obvious in View of the Claims of the Cited Patents.

Reconsideration is requested of the rejection of claims 1-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of Campbell (U.S. Patent No. 6,187,817), claims 1-25 of Campbell (U.S. Patent No. 6,265,386) and claims 1-45 of copending Application No. 10/694,448.

The analysis employed in an obvious-type double patenting rejection parallels the guidelines of a 35 U.S.C. § 103 obviousness determination.[8] However, an important distinction exists. A rejection for obviousness must be based on a comparison of the claimed invention to the entirety of the disclosure in the prior art reference, whereas an obviousness-type double patenting rejection must be grounded on a comparison of the claimed invention to the claims, **and only the claims**, of the reference.[9]

The subject matter of the claims of the present application would not have been obvious in view of the claims of U.S. Patent Nos. 6,187,817 and 6,265,386 and copending U.S. Application 10/694,432. When evaluating the scope of a claim, every element of the claim must be considered.[10] To support an obviousness-type double patenting rejection, there must be some motivation or suggestion in the art to modify the claimed processes the '817 and '386 patents and the '448 application to incorporate the features of the instantly claimed methods. It is respectfully submitted that the Office has failed to establish any such motivation or suggestion, either by citation of a secondary reference or by evidence of the level of skill in the art or the nature of the problem.

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[8]In re Braat, 937 F.2d 589 (Fed. Cir. 1991).

[9]Purdue Pharma L.P. v. Boehringer Ingelheim GMbH, 98 F.Supp.2d 362, 392, 55 USPQ2d 1168, 1190 (S.D.N.Y. 2000), *aff'd*, 237 F.3d 1359, 57 USPQ2d 1647 (Fed. Cir. 2001).

[10]See, e.g., In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

A. U.S. Patent No. 6,187,817

Subject claims 1-29 are directed to methods for preventing or treating ototoxicity, neurotoxicity, alopecia, gastrointestinal disorder, or reduced survival in a patient exposed to radiation, the method comprising administering to said patient an effective amount of a protective agent. In contrast, claims 1-25 of the '817 patent are directed to a method for preventing or treating ototoxicity in a patient undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound comprising administering to said patient an effective amount of an otoprotective agent. Accordingly, as the claims of the '817 patent do not include the element of a "patient exposed to radiation," the claims do not include all the elements of the subject claims. Further, the claims of the '817 patent would not have motivated a person of ordinary skill to select the element of a "patient exposed to radiation" from the universe of possible causes of the toxicities. The claims of the '817 patent only recite anti-tumor platinum-coordination compounds as the cause of ototoxicity. Thus, the subject claims would not have been obvious from the claims of the '817 patent.

B. U.S. Patent No. 6,265,386

The subject claims are detailed above for the '817 patent. Claims 1-25 of the '386 patent are directed to a method for preventing or treating ototoxicity in a patient undergoing treatment with an aminoglycoside antibiotic comprising administering to said patient an effective amount of an otoprotective agent. Accordingly, as the claims of the '386 patent do not include the element of a "patient exposed to radiation," the claims do not include all the elements of the subject claims. Further, the claims of the '386 patent would not have motivated a person of ordinary skill to select the element of a "patient exposed to radiation" from the universe of possible causes of the toxicities. The claims of the '386 patent only recite aminoglycoside antibiotics as the cause of ototoxicity. Thus, the subject claims would not have been obvious from the claims of the '386 patent.

C. U.S. Application Serial No. 10/694,448

As detailed above for both the '817 and '386 patents, the claims of the '448 application are directed to methods for preventing or treating ototoxicity in a patient undergoing treatment with an aminoglycoside antibiotic or a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound comprising administering to said patient an effective amount of an otoprotective agent. Accordingly, the subject claims would not have been obvious from the claims of the '448 application for the same reasons as for the '817 and '386 patents.

In the Office action it is pointed out that the "comprising" form of the instant claims does not positively exclude the administration of the recited sulfur compounds to a patient who is undergoing treatment with an anti-tumor platinum-coordination compound or an aminoglycoside antibiotic. However, this is not the point. The point is that the instant claims affirmatively require administration to a person who is exposed to radiation. Moreover, the claims of the '817 and '386 patents and the '448 application offer no remote teaching or suggestion that D-methionine or any other sulfur compound be administered to a patient exposed to radiation. No secondary reference has been cited to support such rejection, nor has the Examiner identified any knowledge within the skill of the art or any motivation in the nature of the problem which would lead from the claims of the '817 and '386 patents and the '448 application to the instantly claimed method. It is, therefore, respectfully requested that the double patenting rejection over the claims of the '817 and '386 patents and the '448 application be withdrawn.

Information Disclosure Statement

References 8-75 of the Information Disclosure Statement were submitted with Amendment A of U.S. Application Serial No. 10/694,448 for your review.

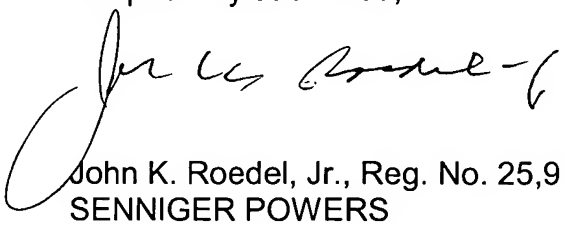
Applicant has simultaneously submitted copies of Office actions received in parent applications U.S. Serial No. 09/057,065 (issued as U.S. Pat. No. 6,265,386) and U.S. Ser. No. 08/942,845 (issued as U.S. Pat. No. 6,187,817) along with copies of the pending claim sets corresponding to each Office action.

CONCLUSION

Applicant submits that the present application is now in a condition for allowance and requests early allowance of the pending claims.

A check in the amount of $225.00 for a two month extension of time is enclosed. The Commissioner is hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,



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